

Attorney Docket No. 6443.500-US
Hansen et al.
Serial No. 10/699,338 Filed October 31, 2003

RECEIVED
CENTRAL FAX CENTER
MAY 14 2007

RESPONSE

The examiner states in the Office Action Summary that claims numbered 1-43 are pending in the application; claims numbered 3, 8-13 and 18-43 are withdrawn from consideration; claims numbered 1, 2, 4-7, and 14-17 are rejected; and claims numbered 1, 2 and 17 are objected to..

Claims numbered 2, 5, 6, 11, 14, 15, 17 and 20 are amended herein. Claims numbered 1, 3, 4, 10, 12, 13, 16, 18, 19, and 21-43 are cancelled herein. New claims numbered 44-49 are added herein. Following entry of the enclosed amendment, claims numbered 2, 5-9, 11, 14, 15, 17, 20, and 44-49 are pending.

- (1) The examiner requests a correction to the specification at page 1, line 6, to insert a proper provisional application serial number.

Applicant has amended the specification as recommended.

- (2) The examiner has objected to claims numbered 1, 2 and 17 for informalities.

Applicant has cancelled claim 1, and amended claims 2 and 17 to address the examiner's objections.

Applicant respectfully requests reconsideration and withdrawal of the objection to claims number 1, 2 and 17.

- (3) The examiner states claims numbered 1, 2, 4-7 and 14-17 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims numbered 1 and 2 are rejected as failing to define the invention in a manner required by 35 U.S.C. §112, second paragraph. The claim(s) are narrative in form and replete with indefinite and functional or operational language. Claims numbered 1, 2, 4-7 and 14-17 are rejected as being incomplete for omitting essential elements: the subject of which the compound is administered to.

Applicant has cancelled claim number 1, and amended claims numbered 2, 14 and 17 to clarify the subject matter of the claims.

Applicant respectfully requests reconsideration and withdrawal of the rejection of claims

Attorney Docket No. 6443.500-US
Hansen et al.
Serial No. 10/699,338 Filed October 31, 2003

number 1, 2, 4-7 and 14-17 under 35 U.S.C. §112, second paragraph.

(4) The examiner states claims numbered 1, 2, 4-7 and 14-16 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, (a) the recitation of the claims encompasses an extremely broad range of compounds without any structural limitation other than the characterization of the compounds having a slope calculated from the equation of claim 1. No structural connection is established between the slope value and the compound. Additionally, (b) "prodrug" encompasses a broad range of compounds. The specification does not provide any structural limitation other than that "prodrug" includes biohydrolyzable amides and biohydrolyzable esters. Further, (c) the claims are very broad due to the vast number of possible diseases/conditions that are described as being "a disease/condition benefiting from an enhancement of mitochondrial respiration."

Applicant has cancelled claim number 1, and amended claim number 2 to include structural limitation and specific diseases/conditions benefiting from an enhancement of mitochondrial respiration. Applicant respectfully submits prodrug forms of the compounds of the invention are readily synthesized utilizing procedures publicly available to those skilled in the art. Since the 1970s numerous prodrugs have been designed and developed. Many publications exist that provide ample guidance to the skilled artisan. [See, for example, conventional procedures for the selection and preparation of suitable prodrug derivatives in "Design of Prodrugs", ed. H. Bundgaard, Elsevier (1985); and mini review: "Prodrug Strategies Based on Intramolecular Cyclization Reactions"; Shan, D. et al. *Journal of Pharmaceutical Sciences Vol. 86, No. 7, pp. 765-767 (1997)*, wherein the cleavage of amide or ester linkages is achieved with esterase-, phosphatase-, or redox-sensitive triggering mechanisms.] Applicant respectfully submits prodrug forms of the compounds of the present invention are readily synthesized with appropriate experimentation commensurate with the skills of those familiar with the art.

Applicant respectfully requests reconsideration and withdrawal of the rejection of claims numbered 1, 2, 4-7 and 14-16 under 35 U.S.C. §112, first paragraph.

(5) The examiner states claims numbered 1, 2, 4-7 and 14-17 are rejected under 35 U.S.C. §103(a) as unpatentable over Bachynsky (U.S. Patent No. 4,673,691) in view of Batt et al. (U.S.

Attorney Docket No. 6443.500-US
Hansen et al.
Serial No. 10/699,338 Filed October 31, 2003

Patent No. 5,593,994) and Rink et al (U.S. Patent No. 5,739,106)

Applicant respectfully submits the examiner has not met the PTO's burden for a *prima facie* case of obviousness. Bachynsky teaches administering 2, 4-dinitrophenol in dosages sufficient to *elevate* the patient's body temperature, while the compounds of Batt et al. are useful as antipyretic agents (body temperature *reducing*). Rink et al. relates to compositions that mimic the body's satiety signals, resulting in reduced food intake. The motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modifications necessary to arrive at Applicant's claimed invention. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. Applicant respectfully submits one skilled in the art would *not* be motivated to combine these teachings to arrive at applicants claimed invention, as the references elicit opposing effects on body temperature.

The examiner states at page 13, lines 7-10, "...[I]t would be obvious to someone of ordinary skill in the art at the time of the instant invention to practice the treatment of Bachynsky in view of Rink et al. with compound modifications in view of Batt et al. to result in the practice of the instant invention with a reasonable expectation of success." Applicant respectfully submits the examiner has taken Applicants invention as a roadmap to find prior art components to combine to arrive at Applicant's claimed invention. The examiner is required to consider the claimed invention as a whole

Applicant has cancelled claims 1, 4, and 16, and amended claims numbered 2, 6 and 17.

Applicant respectfully requests reconsideration and withdrawal of the rejection of claim number 1, 2, 4-7 and 14-17 under 35 U.S.C. §103(a).

Claims numbered 2, 5, 6, 11, 14, 15, 17 and 20 are amended herein. Claims numbered 1, 3, 4, 10, 12, 13, 16, 18, 19, and 21-43 are cancelled herein. New Claims numbered 44-49 are added herein. Following entry of the enclosed amendment, claims numbered 2, 5-9, 11, 14, 15, 17, 20, and 44-49 are pending.

Attorney Docket No. 6443.500-US
Hansen et al.
Serial No. 10/699,338 Filed October 31, 2003

RECEIVED
CENTRAL FAX CENTER
MAY 14 2007

Applicant respectfully requests reconsideration and rejoinder of the withdrawn claims remaining after entry of this amendment.

The examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

Date: May 14, 2007



Rosemarie R. Wilk-Orescan
Registration Number 45,220
Novo Nordisk Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5969

CUSTOMER NUMBER 23650